REMARKS

Entry of this Amendment and consideration of the comments presented herein is respectfully requested.

Claims 1-26 and 28-45 are pending in the application. Claims 1-18 and 28-34 and 43 are under prosecution. Claims 19-26 and 35-37 and 39-42 are withdrawn until such time as a request for rejoinder may appropriately be lodged. Claims 44-45 are added.

Claims 35-42 were indicated in the Office Action Summary and Detailed Action as being withdrawn as directed to non-elected subject matter. Claim 38 is directed to the elected species, SEQ ID NO:4. Therefore, Applicant's request the status of claim 38 be changed from withdrawn to pending.

Claims 1-19, 26, 28, and 32-43 are amended. Applicants submit the amendments to the claims are supported throughout the specification, for example at page 20, line 23-37; at pages 47-49 and Figure 4 of the application as filed, and do not raise any issues of new matter.

New claims 44-45 are supported throughout the specification, including for example, page 43, line 36- page 44, line 9; page 29, lines 12-35; page 31, line 40 – page 35, line 10; and page 49, lines 1-4.

Applicants have amended the specification to add sequence identifiers , trademark designations, and correct typographical errors. Applicants submit these amendments do not raise any issues of new matter.

Double Patenting

Applicants acknowledge the withdrawal of the Obvious-type Double Patenting because the claims of the copending application 10/356,257 are non-obvious over the instant application.

35 U.S.C. § 102

Withdrawal of rejections to claims 1-17 under 35 U.S.C. § 102(b) as being allegedly anticipated by Slabas et al., U.S. Patent No. 5, 843,739 is acknowledged.

35 U.S.C. § 103

Withdrawal of rejections to claims 1-18 and 27-33 under 35 U.S.C. § 103(a) as being allegedly unpatentable over Slabas et al. (U.S. Patent No. 5,843,739) is acknowledged.

Sequence Compliance

A substitute sequence listing in response to the Examiner's remarks accompanies this response. Corresponding amendments to the specification are also made. A copy of the sequence compliance notice is also submitted herewith.

35 U.S.C. § 101

Claims 1-18, 32-34 and 43 are rejected under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter. The claims are amended to include "isolated" as suggested by the Examiner. Applicants request withdrawal of the rejection on this basis.

35 U.S.C. § 112

Claims 1-18, 28-34 and 43 are rejected under 35 U.S.C. § 112¶1 for lack of written description. Applicants respectfully traverse.

Compliance with the written description requirement does not require an applicant to describe exactly the subject matter claimed. Rather, the description must clearly allow a person of ordinary skill in the art to recognize that Applicant invented what is claimed. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). The test is whether the originally filed specification reasonably conveys to a person having ordinary skill in the art that applicant had possession of the subject matter later claimed. In re Kaslow, 217 USPQ 1089 (Fed. Cir. 1991). Moreover, in order to have possession of members of a claimed genus, the specification need not describe all of the species that the genus encompasses. Amgen Inc. v. Chugai Pharmaceutical Co., 18 USPQ2d 1016, 1027 (Fed. Cir. 1991).

Applicants assert that possession of the claimed invention has been shown by description, structures, and figures. Contrary to the assertions in the Office Action, a skilled artisan can envision the detailed chemical structure of the claimed peptides. As indicated above, possession of a claimed genus does not require description of every member. A number of peptides that bind FVIIa are described in the specification by their amino acid sequences. These representative peptides were presented as fusion proteins using phage display and selected for binding to FVIIA. See Table I at page 47 and Table II at page 48 and accompanying description. A number of representative peptides were individually synthesized and further characterized for inhibition of TF-FVIIa activation of FX. See description on page 49 and peptide sequences

provided in Figure 4. Inhibition of FX activation by peptides TF57, TF65, TF100, TF100Z and TF183 is shown in Figure 1. The 5 peptides all demonstrated IC50 values for inhibition of FX activation of less than 100 nM. Further description of the structure and function of peptides is described at page 22, line 38 – page 23, line 14.

In view of the evidence noted above, the specification demonstrates a plurality of compounds that support the claimed genus of FVIIa binding peptides. From the provided chemical structures, the genus of encompassed peptides, including substitution by naturally occurring amino acids or structurally similar amino acid analogs, is within the purview of one skilled in the art. Furthermore, additions and modifications to the N or C terminus of the peptide are also supported, for example by TF100Z (TF100 peptide – Z domain of protein A fusion) and TF183b (biotinylated version of TF183). See, e.g. Figures 3 - 4 and description at page 49, lines 24-28.

The Examiner contends that a biomolecule only described by a function without any known or disclosed correlation between function and structure of the sequence lacks written description. Applicants submit they have provided both the structure of claimed peptides and their function. The structure of several peptides is provided in Figure 4. The ability of some of the peptides to block binding of peptide 183b to Factor VIIa is shown in Figure 3. Inhibition of Factor X activation is shown in Figure 1. Thus, Applicants submit the claimed peptides have been characterized by more than function alone – both structure and function are provided.

The Examiner also contends that the skilled artisan cannot envision the structure of the genus of encoded protein. Applicants disagree. Applicants' claims clearly identify a peptide sequence, where substitutions can be made in the sequence and with what amino acids. Applicants have described and shown several peptides that bind to Factor VIIa in Figure 4. Applicants submit they have provided sufficient description for one of skill in the art to envision the structure of the genus of peptides.

Applicants respectfully request withdrawal of the rejection.

35 U.S.C. § 102(e)

Claims 1-18 are rejected under 35 U.S.C. §102(e) as allegedly anticipated by La Rosa et al. (U.S. Pat. Publication 2004/0214272). Applicants respectfully traverse.

From the information provided with the Office Action, we are unable to confirm that the indicated sequence is from the La Rosa reference and in particular cannot determine which SEQ ID is implicated. Furthermore, the La Rosa reference is a CIP of 09/985,678, filed November 05, 2001, which is a continuation of 09/304,517, filed May 6, 1999. The Examiner claims the May 6, 1999 priority date in making the 102(e) rejection. However, both parent applications were never published. Therefore, priority date of the above-cited clone cannot be ascertained by Applicants. Applicants do not acquiesce to the appropriateness of the La Rosa reference for purposes of anticipation under 35 U.S.C. § 102(e) until such demonstration is made.

Under 35 U.S.C. §102, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

The La Rosa reference teaches 186,000 nucleic acid sequences related to plant husbandry. The predicted protein products of these nucleic acid sequences are also provided. The Office Action asserts that a portion of one of these predicted protein products structurally meet the limitations of claims 1-18. The La Rosa reference does not teach structures for binding to FVIIa or inhibiting FX activation.

The asserted sequence from the provided excerpted search results is presented below.

RN 778249-21-1 HCAPLUS
CN Protein (Arabidopsis thaliana clone ARATH-23APR03-C218984_1.p) (9CI) (CA INDEX NAME)

SEQ
1 MAIIGDALRQ AFMPKQEYES LREEDRAWIK LQRPTLVSIV AFLCFVIFTC
51 TIVSLKIVFP SNVLKRPFCS DIKLQPLPIY GKARDSDLFP GAFYLTDQET
101 VDFYWMAAVV EEDVTFLVSS VYLVAGIFVA YSAPHRHEFL KVVENNYCAS
151 RRGGVRCLSI LNVVFAIIYG LLAIFLGSSL LTLGSSCSVP LFWCYEISSW
201 GLVILYAGTA FSLRRRAALT IDEGEFGNRN DQGLEMLEAN PLEFTPDVER
251 RVNEGFKAWM GPSLLSSDEE EDEPDFYNEV PNVTHTLSSR QRS

The Examiner asserts binding to FVII/FVIIa is an inherent property of the peptides of claim 1.

As an initial matter, Applicants submit that claims 2-5 and 12-18 are not anticipated by the cited LaRosa et al. reference. Applicants submit the peptides of claims 2-5 have a Trp at the Trp_3 position that is not disclosed by the polypeptide of LaRosa et al. Claims 12-14 are directed to peptides that have X_1 and X_K at the N and C terminal ends of the peptide, wherein X_1 is absent or is between 1 and 100 amino acids and X_K is absent or is between 1 and 100 amino

acids. The polypeptide of La Rosa does not have the N and C terminal amino acids as claimed. With respect to claims 15-18, the peptides as claimed have a different sequence, in the least, at the Trp_3 position than the polypeptide disclosed by LaRosa et al. For at least these reasons, Applicants submit the LaRosa et al. reference does not anticipate claims 2-5 and 12-18. Applicants respectfully request withdrawal of the rejection.

Claim 1 specifies Trp_1-Glu_1-Val-Leu-Cys_1-Trp_2-Thr_1-Trp_3-Glu_2-Thr_2-Cys_2-Glu_3-Arg (SEQ ID NO: 4) and various substitutions thereof. Claim 1 is amended to indicate Trp_3 can be substituted with Trp, Tyr, or Phe. The specified sequence of La Rosa does not teach a peptide including Cys-X-X-Trp_3-X-X-Cys as required by amended claim 1 because the residue intermediate between the indicated Cys residues is Ile. Removal of the rejection is respectfully requested.

Summary

Applicants submit that all pending claims are in condition for allowance, and notice to that effect is earnestly requested. The Examiner is invited to contact Applicants' representative at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,
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